

510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: October 18, 2005

510(k) number: K053151

Applicant Information:

Rubicor Medical, Inc.
849 Veterans Blvd.
Redwood City, CA 94063

Contact Person: Ary Chernomorsky
Phone Number: (650) 556-1070
Fax Number: (650) 556-1821

Device Information:

Classification: Class II
Trade Name: Rubicor Magic™ Breast Biopsy Device
Classification Name: Biopsy Instrument (21 CFR 876.1075)

Equivalent Device:

The subject device is substantially equivalent in intended use and/or method of operation to the Ethicon Mammotome® Hand-Held System (K991980), the Sanarus Cassie™ Rotational Core Biopsy System (K042136), and the BIP VacuFlash® Biopsy System (K024089).

Device Description:

The Rubicor Magic Breast Biopsy Device is a sterile, single-use percutaneous biopsy device. The working end of the device includes an 8 cm long, 10 gauge, stainless steel coring cannula and a sharp stylet that runs through the center of the cannula and extends from its distal end. The handle of the device contains an actuation button, two indicator lights, a removable sample collection chamber, a drive mechanism for advancing and rotating the coring cannula and transporting the core specimen to the collection chamber, a DC motor, and a 9 V battery.

Intended Use:

The Rubicor Magic Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses.

The Rubicor Magic™ Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Test Results:*Performance*

Results of in-vitro testing demonstrate that the Rubicor Magic Breast Biopsy Device is safe and effective for its intended function.

Biocompatibility

The materials used in the Rubicor Magic™ Breast Biopsy Device meet the requirements of ISO 10993-1.

Summary:

Based on the intended use, product, and performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed and unmodified predicate device.

Indication for Use Statement

510(k) Number (if known): K053151

Device Name: Rubicor Magic™ Breast Biopsy Device

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √
(Per 21 CFR 801.109)

OR

Over-the Counter Use _____



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2005

Rubicor Medical, Inc.
c/o Morten Simon Christensen
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K053151

Trade/Device Name: Rubicor Magic™ Breast Biopsy Device
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: November 8, 2005
Received: November 10, 2005

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

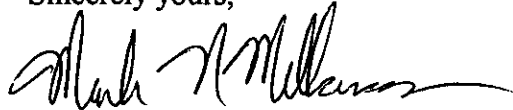
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement510(k) Number (if known): K053151Device Name: Rubicor Magic™ Breast Biopsy Device

Indications for Use:

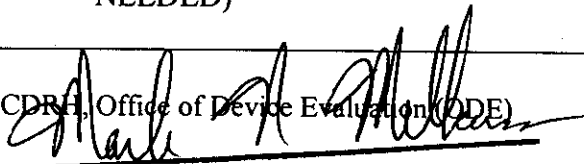
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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K053151Prescription Use √
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